



## ENZYMATIC THERAPY

INCORPORATED

*What Better feels like.™*

### INTEGRATIVE THERAPEUTICS INC.™

NF Formulas • PhytoPharmica  
Tyler Encapsulations • Vitaline Formulas

9755 SW Commerce Circle, Suite B2

Wilsonville, OR 97070

P: 503.582.8386 • F: 503.582.0467

### ENZYMATIC THERAPY®

&  
**PHYTOPHARMICA®**

825 Challenger Drive, Green Bay, WI 54311-8328

P: 920.469.1313 • F: 888.570.6460 (Enzymatic)

P: 920.469.9099 • F: 920.469.4418 (Phyto)

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June 12, 2005

Office of Nutritional Products, Labeling &  
Dietary Supplements, HFS 810  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
5100 Paint Branch Parkway  
College Park, MD 20740

JUL 26 2005

RE: Label Claims/Disclaimers

Dear Sir or Madam:

This letter is to notify you that the following product is Manufactured, Packed, and/or Distributed by Enzymatic Therapy, Inc. at 825 Challenger Drive, Green Bay, Wisconsin 54311 has a label that contains a statement provided by section 403(r)(6) of the Federal Food, Drug and Cosmetic Act. Enzymatic Therapy, Inc. wishes to take advantage of the exemption to section 201(g)(1)(C) of the act and comply with section 403(r)(6) of the act. These claims are not necessarily for a product we currently market or plan to market in the immediate future, and may be exploratory in nature.

PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
HDL Booster™*	Shown to reduce homocysteine levels, which is important for heart health.*	Vitamin C (ascorbic acid), Vitamin E (mixed d-alpha tocopherols), Niacin (niacinamide), Vitamin B6 (pyridoxine HCl), Folic Acid, Vitamin B12 (cyanocobalamin), Magnesium (from Magnesium amino acid chelate), Selenium (L-Selenomethionine), L-Arginine (from L-arginine HCl), L-Carnitine (from L-carnitine L-tartrate), Coenzyme Q10 (CoQ10) (ubiquinone 10), Policosanol, Hawthorn Berry Extract, Taurine, Garlic, Grape Seed Extract, Grape Skin Extract, N-acetyl-L-cysteine, Alpha Lipoic Acid, Soy Isoflavones, Tocotrienols

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

By: \_\_\_\_\_

Robert Doster

Title: Senior Vice President of Scientific Affairs

Date: \_\_\_\_\_

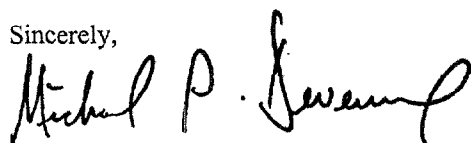
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If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs at (920) 406-3608.

Sincerely,

A handwritten signature in black ink, appearing to read "Michael P. Devereux". The signature is fluid and cursive, with a large initial "M" and a stylized "D".

Michael P. Devereux  
Chief Financial Officer



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July 14, 2005

Office of Nutritional Products, Labeling &  
Dietary Supplements, HFS 810  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
5100 Paint Branch Parkway  
College Park, MD 20740


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PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
HDL Booster™*	Shown in a clinical study conducted at Scripps Memorial Hospital to raise HDL (good cholesterol) levels*	Vitamin C (ascorbic acid), Vitamin E (mixed d-alpha tocopherols), Niacin (niacinamide), Vitamin B6 (pyridoxine HCl), Folic Acid, Vitamin B12 (cyanocobalamin), Magnesium (from Magnesium amino acid chelate), Selenium (L-Selenomethionine), L-Arginine (from L-arginine HCl), L-Carnitine (from L-carnitine L-tartrate), Coenzyme Q10 (CoQ10) (ubiquinone 10), Policosanol, Hawthorn Berry Extract, Taurine, Garlic, Grape Seed Extract, Grape Skin Extract, N-acetyl-L-cysteine, Alpha Lipoic Acid, Soy Isoflavones, Tocotrienols

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

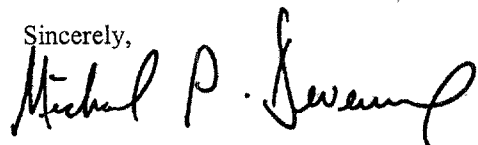
By: 

Robert Doster  
Title: Senior Vice President of Scientific Affairs

Date: \_\_\_\_\_

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs at (920) 406-3608.

Sincerely,

A handwritten signature in black ink, reading "Michael P. Devereux". The signature is fluid and cursive, with the first name "Michael" being the most prominent.

Michael P. Devereux  
Chief Financial Officer



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June 11, 2005

Office of Nutritional Products, Labeling &  
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PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
HDL Booster™*	Recent studies have identified HDL levels as an independent important factor for heart health.*	Vitamin C (ascorbic acid), Vitamin E (mixed d-alpha tocopherols), Niacin (niacinamide), Vitamin B6 (pyridoxine HCl), Folic Acid, Vitamin B12 (cyanocobalamin), Magnesium (from Magnesium amino acid chelate), Selenium (L-Selenomethionine), L-Arginine (from L-arginine HCl), L-Carnitine (from L-carnitine L-tartrate), Coenzyme Q10 (CoQ10) (ubiquinone 10), Policosanol, Hawthorn Berry Extract, Taurine, Garlic, Grape Seed Extract, Grape Skin Extract, N-acetyl-L-cysteine, Alpha Lipoic Acid, Soy Isoflavones, Tocotrienols

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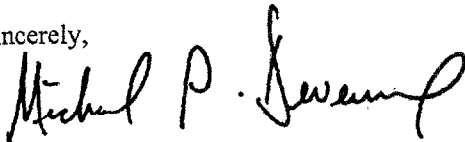
Robert Doster

Title: Senior Vice President of Scientific Affairs

Date: \_\_\_\_\_

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Sincerely,

A handwritten signature in black ink, reading "Michael P. Devereux". The signature is fluid and cursive, with the first name "Michael" and last name "Devereux" clearly legible, and "P." in the middle.

Michael P. Devereux  
Chief Financial Officer